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NOTICE OF ALLOWANCE AND FEE(S) DUE

23117 7590 06/08/2009

NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

EXAMINER

GUSSOW, ANNE

ART UNIT

PAPER NUMBER

1643

DATE MAILED: 06/08/2009

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/579,445

10/04/2006

Christer Nordstedt

GRT/117-580

6580

TITLE OF INVENTION: ANTIBODIES BINDING TO A C-TERMINAL FRAGMENT OF APOLIPOPROTEIN E

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$300	\$0	\$1810	09/08/2009

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

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B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

**Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE
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INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

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23117 7590 06/08/2009

NIXON & VANDERHYE, PC
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I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/579,445	10/04/2006	Christer Nordstedt	GRT/117-580	6580

TITLE OF INVENTION: ANTIBODIES BINDING TO A C-TERMINAL FRAGMENT OF APOLIPOPROTEIN E

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$300	\$0	\$1810	09/08/2009

EXAMINER	ART UNIT	CLASS-SUBCLASS
GUSSOW, ANNE	1643	530-387300

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

- (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, 1 _____
- (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 2 _____
- 3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
- ☐ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies _____

4b. Payment of Fee(s); (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

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Date _____

Typed or printed name _____

Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/579,445	10/04/2006	Christer Nordstedt	GRT/117-580	6580
23117	7590	06/08/2009	EXAMINER	
NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203			GUSSOW, ANNE	
			ART UNIT	PAPER NUMBER
			1643	
DATE MAILED: 06/08/2009				

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Notice of Allowability	Application No.	Applicant(s)	
	10/579,445	NORDSTEDT ET AL.	
	Examiner	Art Unit	
	ANNE M. GUSSOW	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 17 February 2009.
2. ☒ The allowed claim(s) is/are 1-6,9,20,21,28-33,38-41,51-55,59,68 and 70.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 - * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| <ol style="list-style-type: none"> 1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date <u>2/23/09</u> 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | <ol style="list-style-type: none"> 5. <input type="checkbox"/> Notice of Informal Patent Application 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input type="checkbox"/> Other _____. |
|---|--|

/David J Blanchard/
Primary Examiner, Art Unit 1643

EXAMINER'S AMENDMENT

Election/Restrictions

1. Claims 1, 4, 9, 20, 21, 28-33, 38-41, 51-55, 59, 68, and 70 are allowable. The restriction requirement, as set forth in the Office action mailed on October 10, 2007, has been reconsidered in view of the allowability of claims to the elected invention pursuant to MPEP § 821.04(a). However, claims 42-50, 61-63, and 69, directed to patentably distinct antibodies remain withdrawn from consideration because they do not require all the limitations of an allowable claim. Claims 42-50, 61-63, and 69 are cancelled as being drawn to non-elected inventions, as set forth in the examiner's amendment to the claims below.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on February 23, 2009 was filed after the mailing date of the first action on the merits on January 4, 2008. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner and an initialed copy of the IDS is included with the mailing of this office action.

3. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Gary Tanigawa, applicant's representative on June 4, 2009.

The application has been amended as follows:

The claims have been amended to read:

1. (currently amended) An isolated human, humanised or chimeric antibody or antibody fragment, which antibody or fragment:
 - (i) binds to a polypeptide having the amino acid sequence shown in SEQ ID NO: 1 of the C-terminal domain of Apolipoprotein E (ApoE-CTD) or the amino acid sequence of a part thereof;
 - (ii) binds to human plaques; and
 - (iii) comprises:
 - (a) a heavy chain CDR3 region comprising the sequence shown in SEQ ID NO: 26, SEQ ID NO: 20, SEQ ID NO: 23, SEQ ID NO: 207, SEQ ID NO: 208, SEQ ID NO: 209, SEQ ID NO: 210, or SEQ ID NO: 512, or an affinity matured variant thereof;
 - (b) a heavy chain CDR2 region comprising the sequence shown in SEQ ID NO: 25, or an affinity matured variant thereof;
 - (c) a heavy chain CDR1 region comprising the sequence shown in SEQ ID NO: 24, or an affinity matured variant thereof;
 - (d) a light chain CDR3 region comprising the sequence shown in SEQ ID NO: 35, or an affinity matured variant thereof;
 - (e) a light chain CDR2 region comprising the sequence shown in SEQ ID NO: 34, or an affinity matured variant thereof; and
 - (f) a light chain CDR1 region comprising the sequence shown in SEQ ID NO: 33, or an affinity matured variant thereof.
2. (previously presented) An antibody or antibody fragment according to claim 1, wherein said heavy chain CDR3 region comprises an affinity matured variant of SEQ ID NO: 26 having the sequence shown in SEQ ID NO: 512.
3. (previously presented) An antibody or antibody fragment according to claim 1, wherein said heavy chain CDR3 region comprises an affinity matured variant of SEQ ID NO: 26 having the sequence shown in SEQ ID NO: 20.
4. (previously presented) An antibody or antibody fragment according to claim 1 wherein said heavy chain CDR3 region comprises the sequence shown in SEQ ID NO: 23.
5. (previously presented) An antibody or antibody fragment according to claim 2 wherein said heavy chain CDR3 region comprises an affinity matured variant of

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SEQ ID NO: 26 having the sequence shown in SEQ ID NO: 207, SEQ ID NO: 208, SEQ ID NO: 209 or SEQ ID NO: 210.

6. (previously presented) An antibody or antibody fragment according to claim 5, wherein said heavy chain CDR3 region comprises an affinity matured variant of SEQ ID NO: 26 having the sequence shown in SEQ ID NO: 207, SEQ ID NO: 208 or SEQ ID NO: 209.

7-8. (canceled)

9. (previously presented) An antibody or antibody fragment according to claim 1, wherein said polypeptide having the amino acid sequence of a part of SEQ ID NO: 1 comprises the sequence shown in SEQ ID NO: 5.

10-19. (canceled)

20. (previously presented) An antibody or antibody fragment according to claim 1, wherein said ApoE-CTD polypeptide is a recombinant polypeptide.

21. (previously presented) An antibody or antibody fragment according to claim 20, wherein said recombinant polypeptide is biotinylated.

22-27. (canceled)

28. (previously presented) An antibody or antibody fragment according to claim 1, which binds to said plaques in the presence of VLDL.

29. (previously presented) An antibody or antibody fragment according to claim 1, wherein said VLDL is present in human plasma.

30. (original) An antibody or antibody fragment according to claim 29, which binds to the plaques in the presence of 25% plasma.

31. (original) An antibody or antibody fragment according to claim 30, which binds to the plaques in the presence of from 25% to 50% plasma.

32. (original) An antibody or antibody fragment according to claim 31, which binds to the plaques in the presence of 50% plasma.

33. (previously presented) An isolated antibody or antibody fragment which comprises:

- (a) the heavy chain sequence shown in SEQ ID NO: 40 and the light chain sequence shown in SEQ ID NO: 518 and/or 519 or
- (b) the heavy chain sequence shown in SEQ ID NO: 40 and the light chain sequence shown in SEQ ID NO: 520 and/or 521.

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34-37. (canceled)

38. (previously presented) An isolated antibody or antibody fragment which comprises:

- (a) the heavy chain CDR1 sequence shown in SEQ ID NO: 24, the heavy chain CDR2 sequence shown in SEQ ID NO: 25 and the heavy chain CDR3 sequence shown in any one of SEQ ID NOS: 207, 209 and 210; and
- (b) the light chain CDR1, CDR2 and CDR3 sequences shown in SEQ ID NOS: 33, 34 and 35, SEQ ID NOS: 219, 247 and 269, SEQ ID NOS: 226, 252 and 275 or SEQ ID NOS: 218, 34 and 268.

39. (previously presented) An antibody or antibody fragment according to claim 38, wherein the heavy chain CDR3 region comprises the sequence shown in SEQ ID NO: 210 and the light chain comprises the sequences shown in SEQ ID NOS: 33, 34 and 35, the heavy chain CDR3 region comprises the sequence shown in SEQ ID NO: 209 and the light chain comprises the sequences shown in SEQ ID NOS: 219, 247 and 269 or SEQ ID NOS: 218, 34 and 268, or the heavy chain CDR3 region comprises the sequence shown in SEQ ID NO: 207 and the light chain comprises the sequence shown in SEQ ID NOS: 226, 252 and 275.

40. (previously presented) An antibody or antibody fragment according to claim 38, wherein the heavy chain comprises the sequence shown in any one of SEQ ID NO: 317, 318 or 319.

41. (previously presented) An antibody or antibody fragment according to claim 38, wherein the light chain comprises the sequence shown in SEQ ID NO: 43, 295, 294 or 304.

42-50. (canceled).

51. (previously presented) An antibody or antibody fragment according to claim 1, wherein said antibody is an IgG.

52. (previously presented) An antibody or antibody fragment according to claim 1, wherein said antibody fragment is a Fab fragment or scFv.

53. (previously presented) An antibody or antibody fragment according to claim 1, which is a monoclonal antibody.

54. (previously presented) An antibody or antibody fragment according to claim 1, which is a humanised antibody.

55. (previously presented) An antibody or antibody fragment according to claim 1, which is chimeric.

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56-58. (canceled)

59. (previously presented) A pharmaceutical composition comprising an antibody or antibody fragment according to claim 1 and a pharmaceutically acceptable carrier or diluent.

60-67. (canceled)

68. (previously presented) A kit for detecting ApoE-CTD, which kit comprises an antibody or antibody fragment according to claim 1 and means for detecting said an antibody or antibody fragment.

69. (canceled)

70. (previously presented) An antibody or antibody fragment according to claim 1, which is a human antibody.

The specification has been amended as follows:

Page 75 lines 11-31 have been replaced with the following paragraphs:

Indeed, preliminary IHC data shows that four of these Fabs possibly bind to tissue in AD patients. These four Fabs all bind to peptide 4 and not to the overlapping peptides, suggesting that they recognise similar (overlapping) epitopes (group 1), probably epitope containing amino acids of LVEDMQRQ (SEQ ID NO: 12) or a secondary structure only present in peptide 4 and plaques.

Two other Fabs, positive in IHC and selected on peptide 4, bind to peptides 4 and 9 and to a conformation that is not present or not as prevalent in bCTD. Possibly the epitope for these two antibodies include sequence MQRQWAGL (SEQ ID NO: 13, group 2).

Another Fab possibly positive in IHC, selected on peptide 9, only recognises peptide 9 and not overlapping peptide nor bCTD and could recognise either the epitope WAGLVEKV (SEQ ID NO: 14) or a conformation only present in peptide 9 (group 3) and plaques.

One Fab binds to peptide 1, 6 and bCTD. This epitope (RTRDRLDE, SEQ ID NO: 15) is not predicted to be inside of the binding site of VLDL (group 4).

Two antibodies, obtained from selections on peptides 4 and 9, recognise both peptides (epitope MQRQWAGL, SEQ ID NO: 13) and CTD and therefore are different from Fabs of group 2 (group 5).

One antibody, selected to peptide 8, binds to peptide 4, 8 (epitope WFEPLVED, SEQ ID NO: 16) and bCTD (group 6).

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5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNE M. GUSSOW whose telephone number is (571)272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anne M. Gussow
June 4, 2009

/Anne M Gussow/
Examiner, Art Unit 1643

/David J Blanchard/
Primary Examiner, Art Unit 1643